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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,500	06/15/2006	Jean-Francois Bonfanti	TIP-0053USPCT	7371
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JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA			MCDOWELL, BRIAN E	
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			1624	
			MAIL DATE	DELIVERY MODE
			02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Comments	10/596,500	BONFANTI ET AL.			
Office Action Summary	Examiner	Art Unit			
	BRIAN MCDOWELL	1624			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on					
•	-· action is non-final.				
<i>,</i> —	· 				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
·		0 0.0. 2.0.			
Disposition of Claims					
 4) Claim(s) 1-14,16,17,19 and 20 is/are pending in the application. 4a) Of the above claim(s) 6,7,17 and 19 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-5, 8-14, 16, and 20 is/are rejected. 7) Claim(s) is/are objected to. Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) One of References Cited (PTO-892)					

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-14, 16 and 20, drawn to compounds of the general formula (I) seen in claim 1 and simple compositions thereof wherein R^1 = pyridyl.
- II. Claims 1-14, 16 and 20, drawn to compounds of the general formula (I) seen in claim 1 and simple compositions thereof not embraced by group I.
- III. Claims 17 and 19, drawn to a process of synthesizing compounds/compositions in either groups I or II (applicant must elect which compound group).

Note: Election of a single disclosed chemical specie is required for any group elected.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The prior art by Janssens *et al.* (WO 01/00611), which is mentioned in the ISR, teach several

compounds that read on claim 1 (see page 87, table 13). Therefore, the compounds and methods are not novel and the invention lacks a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

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above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. During a telephone conversation with Mary Appollina on 2/9/2009, a provisional election was made with traverse to prosecute the invention of group I, claims 1-14, 16 and 20. Applicant also provisionally elected the specie of compound 4 (table 1 of the specification). The elected specie reads on claims 1-5, 8-14, 16, and 20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6, 7, 17, and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

This application contains claims drawn to an invention nonelected with traverse in the reply on 2/9/2009. A complete reply to this action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Applicant's elected specie was found free of the prior art, thus the full scope of the claims were examined.

An action of the merits of claims 1-5, 8-14, 16, and 20.

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Priority

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This application receives the earliest foreign priority date of 12/18/2003, drawn to foreign application EP 03104804.4.

Specification

The abstract of the disclosure is objected to because of the following:

Applicant is advised that the abstract of the disclosure should not exceed 150 words.

Applicant is advised to shorten the content of the abstract to correct this problem.

See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 8-14, 16, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-32, and 34-36 of copending Application No. 12/030483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species encompassed within these claims are obvious over each other.

For instance, in reference to claim 22 of application '483, when R^{3b} = Me, R^{5} = H, $G = CH_{2}$, Q = methyl (connected to piperidinyl), and R^{1} = pyridyl, this compound would simply be a regioisomer to a specie wherein R^{2a} = Me, $R^{2b,3a,3b}$ = R^{5} = H, $G = CH_{2}$, Q = methyl substituted piperidinyl, and R^{1} = pyridyl in claim 1 of the instant application. However, MPEP states the following:

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Claims 34 and 35 are drawn to methods of use employing obvious compounds, since there was not a prior restriction between the compounds and their methods of use, the methods are considered obvious.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 8-14, 16, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Application No. 10/596521 (claims 1-30 and 34-39). Additionally, these claims are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over US Patents 7,355,051 (claims 1-8) and 5,360,807 (claims 1-4) for similar reasons stated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8-13, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssens *et al.* (WO 01/00611)-mentioned in IDS.

The following specie may be encompassed by the aforementioned claims:

wherein R^1 = disubstituted pyridyl with amino and hydroxyl, $R^{2a,2b,3a,3b}$ = R^5 = H, G = CH_2 , Q = C_4 alkyl substituted with hydroxyl.

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Janssens et al. teach the compound below (see page 88, compound 313):

wherein R^1 = disubstituted pyridyl with hydroxyl and methyl, $R^{2a,2b,3a,3b}$ = R^5 = H, $G = CH_2$, $Q = C_3$ alkyl substituted with hydroxyl and amino.

The only difference between applicant's compound and the compound in the Janssens document is how the amino and methyl moieties are substituted on the molecule (i.e., moieties are switched in respect to their positions). These strikingly similar compounds are considered positional isomers and both possess the same therapeutic utility as inhibitors of respiratory syncytial virus replication. In regards to the former (positional isomers), MPEP 2144.09 states

"Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

In summary, applicant is taking a well-known compound that is described in the literature and executing a simple synthetic transformation (forming a positional isomer). Both compounds have the same utility, and it would be expected that based on the teachings above that a compound with similar biological activity would have been obtained.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-14, 16, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salts, stereochemically isomeric forms, and prodrugs of the claimed compounds, does not reasonably provide

enablement for *N*-oxides, quaternary amines and metal complexes of the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see In re Vaeck, 20 USPQ2d 1438, 1444. Analysis is described below:

(A) Breadth of claims: The claims are drawn to compounds of the formula I and their *N*-oxides, quaternary amines and metal complexes of compounds of the formula I. Thus, the scope is very large.

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(B) The nature of the invention: Amino-benzimidazoles (and their corresponding *N*-oxides, quaternary amines and metal complexes) as inhibitors of respiratory syncytial virus replication.

(C) State of the Prior Art: Chemistry is unpredictable. See In Re Marzocchi and Horton 169 USPQ at 367 paragraph 3:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such workChemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)" Dorwald F. A. Side Reactions in Organic Synthesis, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

The examiner did not find a single *N*-oxide, quaternary amine or metal complex of an amino-benzimidazole in the prior art that is structurally similar to the instantly claimed compounds.

- (D) Skill of those in the art: The level of skill in the art is high and one would possess a Ph.D. in synthetic organic chemistry.
- (E) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and

physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

- (F) Direction or Guidance: Little guidance or direction is provided by applicant in reference to making *N*-oxides, quaternary amines and metal complexes of the instantly claimed compounds. Due to the insufficient amount of guidance, one of ordinary skill would expect undue experimentation in obtaining these various forms of the instantly claimed compounds.
- (G) Working Examples: The compound core depicted with specific substituents represent a narrow subgenus for which applicant has provided sufficient guidance to make and use; however, this disclosure is not sufficient to allow extrapolation of the limited examples to enable the scope of the compounds instantly claimed. Applicant has provided no working examples of any compounds where the compound of formula I contained a *N*-oxide, quaternary amine or a metal complex.

Within the specification, "specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP 608.01(p).

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high

and burdensome. Applicant fails to provide guidance and supporting information for making the thousands of other compounds which are encompassed by the claims, therefore undue experimentation would be expected.

Due to the level of unpredictability in the art, the very limited guidance provided, and the lack of working examples, the applicant has shown lack of enablement. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claims 1,4,5,8-14, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds where $G = C_{1-1}$ alkanediyl, does not reasonably provide enablement for compounds where G = a direct bond. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the factors addressed previously above to determine whether undue experimentation is required:

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Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see In re Vaeck, 20 USPQ2d 1438, 1444. Analysis is described below:

(A) Breadth of claims: The claims are drawn to compounds of the formula I where $G = C_{1-10}$ alkanediyl or a direct bond .

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(C) State of the Prior Art: Chemistry is unpredictable. See In Re Marzocchi and Horton 169 USPQ at 367 paragraph 3:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such workChemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)" Dorwald F. A. Side Reactions in Organic Synthesis, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

The examiner did not find a single compound in the prior art where the imidazole ring of formula I was directly bonded to a pyridyl ring.

(D) Skill of those in the art: The level of skill in the art is high and one would possess a Ph.D. in synthetic organic chemistry.

(E) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

- (F) Direction or Guidance: Little guidance or direction is provided by applicant in reference to making or using compounds where G is a direct bond. Due to the insufficient amount of guidance, one of ordinary skill would expect undue experimentation in obtaining the instantly claimed compounds.
- (G) Working Examples: The compound core depicted with specific substituents represent a narrow subgenus for which applicant has provided sufficient guidance to make and use; however, this disclosure is not sufficient to allow extrapolation of the limited examples to enable the scope of the compounds instantly claimed. Applicant has provided no working examples where the compounds of formula I possessed the limitation where G = a direct bond.

Within the specification, "specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP 608.01(p).

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome. Applicant fails to provide guidance and supporting information for making the thousands of other compounds which are encompassed by the claims, therefore undue experimentation would be expected.

Due to the level of unpredictability in the art, the very limited guidance provided, and the lack of working examples, the applicant has shown lack of enablement. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ВМ

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624